UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,226	06/25/2004	Toshitada Noguchi	2004-1003A	7469

513 7590 04/06/2007

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	**PAPER NUMBER**
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,226	NOGUCHI ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *2-7 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8-12 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-14 are pending. Applicant should note that the examiner for the case has changed.

Election/Restrictions

Applicant's elections of the species "2-amino-6-substituted purine" as the reacted compound in claims 1, 2, and 5; "2-amino-6-halogenopurine" as the 2-amino-6-substituted purine in claims 11 and 13; "thymidine" as the 2'-deoxynucleoside in claims 3, 4, 6, 7, 9, and 14; "nucleoside deoxyribosyl transferase II" as the transferase in claims 3, 6, and 9; and "deaminase" as the hydrolase in claims 2, 5, and 8 in the reply filed on 1/19/07 are acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 2-7 and 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. These claims all recite nonelected species of the compounds and/or enzymes or depend entirely from parent claims that do so. Election was made **without** traverse in the reply filed on 1/19/07.

Examination on the merits will commence at this time on claims 1, 8-12, and 14 ONLY, to the extent they read on the elected species where applicable.

Specification

The abstract of the disclosure is objected to because it comprises more than a single paragraph and it is replete with legal language such as that found in claims. The

second paragraph also fails to comply with the rules of standard English. Correction is required in the form of a replacement abstract with the reply to this Office action. See MPEP § 608.01(b).

Applicant is reminded of the proper content, language, and format of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The **abstract should not refer to purported merits** or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

The abstract should be in **narrative form** and generally limited to a **single paragraph** on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. **The form and legal phraseology often used in patent claims**, such as "means" and "said," **should be avoided**. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Objections

Claim 10 is objected to because of the following informalities: The word "hydrolyzable" is misspelled at line 3. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 8-12, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a process for producing 2'-deoxyguanosine (dR-Gua) but lacks a step in which dR-Gua is actually produced and a step in which dR-Gua is recovered from the reaction mixture. The single step in the claimed method ("reacting") does not match the scope of the preamble. Clarification is required. While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the **complete** process since the recovery step is missing from the claims. Clarification is required. The metes and bounds of the claimed process are therefore not clearly established or delineated. The examiner suggests that the phrase "to yield 2'-deoxyguanosine and recovering said 2'-deoxyguanosine" be added to the claim.

Furthermore, claim 1 requires that a 2-amino-6-substituted purine (2-AP) and 2'-deoxynucleoside (dR-B) be reacted "in the presence of" two enzymes, but the claim does not require that these two enzymes actually participate in the reaction. Clarification is required. The examiner suggests that "in the presence of" be replaced with "with" or, at least, that the claim be amended to require that the two particular enzymes recited in claim 1 catalyze the reaction between 2-AP and dR-B to yield dR-Gua.

Claim 10 requires that the 2-AP have "a substituent which is hydrolyzable," but the claim provides no point of comparison for this relative term, for example "hydrolyzable by *E. coli* adenosine deaminase." It is not clear which groups are considered "hydrolyzable" and which are not. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8-10, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Yokozeki et al. (2001, U.S. Patent 6,197,552; reference AA on 6/25/04 IDS) taken in light of information from DBGET ("Reaction R02806," reference U; retrieved from the Internet <URL: http://www.genome.ad.jp/dbget-bin/www_bget?reaction+R02806>).

Yokozeki et al. (2001) teach a process for preparing 2'-deoxyguanosine (dR-Gua) by contacting 2,6-diaminopurine (a 2-amino-6-substituted purine in which the substitution at position 6 is an amino group) and thymidine (a 2'-deoxyribonucleoside)

with a microorganism that produces an enzyme that produces 2,6-diaminopurine-2'-deoxyriboside from said 2,6-diaminopurine and thymidine (column 2, lines 7-30 and 45-53; column 4, line 63, through column 5, line 5; Example 3 at column 9, line 55, through column 10, line 8); and then adding adenosine deaminase to the 2,6-diaminopurine-2'-deoxyriboside to yield dR-Gua (column 2, lines 31-37; column 7, lines 22-25; Example 4 at column 10, lines 10-25). Information from DBGET is cited as evidence that an enzyme that produces 2,6-diaminopurine-2'-deoxyriboside from said 2,6-diaminopurine and thymidine is inherently a nucleoside deoxyribosyltransferase.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 8-12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yokozeki et al. (2001) taken in view of information from DBGET (reference U), Yokozeki et al. (1989, U.S. Patent 4,835,104; reference A), and Burns et al. (1997, U.S. Patent 5,637,574; reference B).

As discussed above in the rejection under 35 U.S.C. § 102, Yokozeki et al. (2001) teach a process for preparing 2'-deoxyguanosine (dR-Gua) by contacting 2,6-diaminopurine (a 2-amino-6-substituted purine in which the substitution at position 6 is an amino group) and thymidine (a 2'-deoxyribonucleoside) with a microorganism that produces an enzyme that produces 2,6-diaminopurine-2'-deoxyriboside from said 2,6-diaminopurine and thymidine (column 2, lines 7-30 and 45-53; column 4, line 63, through column 5, line 5; Example 3 at column 9, line 55, through column 10, line 8); and then adding adenosine deaminase to the 2,6-diaminopurine-2'-deoxyriboside to yield dR-Gua (column 2, lines 31-37; column 7, lines 22-25; Example 4 at column 10, lines 10-25).

Information from DBGET is cited as evidence that an enzyme that produces 2,6-diaminopurine-2'-deoxyriboside from said 2,6-diaminopurine and thymidine is inherently a nucleoside deoxyribosyltransferase.

Yokozeki et al. (2001) do not teach or suggest a process in which the 2-amino-6-substituted purine is a 2-amino-6-halogenopurine, specifically 2-amino-6-chloropurine, as in claims 11 and 12.

Yokozeki et al. (1989) teach a process for preparing 2',3'-dideoxyguanosine by contacting a microorganism with a base and 2',3'-dideoxyuridine (column 5, lines 16-27; column 8, line 66, through column 9, line 3; claim 10). The microorganism used in the process of Yokozeki et al. (1989) produces an enzyme that transfers the ribosyl group of 2',3'-dideoxyuridine to the base (column 5, lines 25-27; and column 8, lines 18-26).

The base of Yokozeki et al. (1989) may be 2,6-diaminopurine or 2-amino-6-chloropurine (column 6, line 67, through column 7, line 9, especially lines 2-3).

Burns et al. teach that a chloro group at the 6-position of purines is a reactive leaving group that facilitates nucleophilic substitution at the 6-position (column 10, lines 38-41).

A person of ordinary skill in the art would have had a reasonable expectation of success in substituting 2-amino-6-chloropurine for 2,6-diaminopurine in the process of Yokozeki et al. (2001) because Yokozeki et al. (1989) teach that 2-amino-6-chloropurine and 2,6-diaminopurine are functional equivalents in ribosyltransferase-catalyzed reactions. The skilled artisan would have been motivated to substitute 2-amino-6-chloropurine for 2,6-diaminopurine because Burns et al. teach that a chloro group at the 6-position of a purine is reactive.

The selection of substituted base in the method of Yokozeki et al. (2001) would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Yokozeki et al. (1989) establish 2-amino-6-chloropurine and 2,6-diaminopurine as functional equivalents in ribosyltransferase-catalyzed reactions. A holding of obviousness over the cited claims is therefore clearly required.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

No claims are allowed. No claims are free of the art.

Applicant is requested to specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP

714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lora E Barnhart